MAY 3 0 2001

K011111
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X. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA. (Separate Page)

A. Submitter: S.B.B. Desemberg, Modular X-Ray Devices, Roodepoort, South Africa. Phone/fax: 27 11 794 5523.

I. Classification name and number: Stationary X-ray System, KPR

II. Common/Usual Name. General Radiographic System.

III. Proprietary Name: MXD 100/MX 20, or MX 30, or MX 40, or MX 50.

IV. Classification: Class II, CFR 892.1680, Stationary X-ray System

V. Establishment Registration Number: In process.

VI. Compliance with Performance Standards: Conform to Diagnostic Equipment Standard, 21 CFR 1020.30 and 1020.31.

VII. Description of the Device: The MXD stationary x-ray system is a general radiography system designed specifically for a wide variety of uses in primary care. The special shape of the stand offers the possibility for lateral exposure with a patient lying on the mobile support. The MXD100 keeps the advantages of the World Health System with variable source-image distance and a fixed position of the film receptor to provide optimal geometry and minimal equipment adjustment. A lateral floating table top movement, when used in conjunction with the parallel tracking of the table wheels provides a 4-way table movement for ease of patient positioning

VIII. Substantial Equivalence: The Modular X-ray Devices series MXD100 are substantially equivalent (and nearly identical) to the Vertical Integrated Perfect View (VIP) Radiology system cleared by Bennett X-Ray Corp. (subsidiary of Trex Medical Corp) in K952672. The Modular system is also substantially equivalent to HFG 350, 650, 1050 cleared by Varian of Canada in K923455; and the Floor Mount Tubestand-Performer-N 6610.1 cleared by the Continental X-ray Corp. The integrated C-Arm of the MXD 100 series is equivalent to the C-Arm in the VIP system cleared in K952672, and to the C-Arm cleared by Trex Medical Corp. in K982427

The "510(k) substantial Equivalence" Decision Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the <u>same intended use</u> as the predicate devices listed above.

2. The <u>technological characteristics</u> for this product are the same as those for the predicate devices and those currently on the market. The components have FDA Accession numbers or 510(k) numbers.

3. Descriptive information provided shows that the materials and components of which the MXD 100 system is comprised are substantially equivalent and very similar to predicate devices currently on the market.

4. The FDA "Decision-Making Process chart was used.

(End of Summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2001

Mr. S.B. Desemberg
Partner
Modular X-Ray Devices
P.O. Box 2878
Honeydew 2040
ROODEPOORT SOUTH AFRICA

Re: K011111
MXD100/MX 20, MX 30, MX 40,
or MX 50 – (MXD 100 Series)
Dated: April 4, 2001
Received: April 11, 2001
Regulatory Class: II
21 CFR §892.1680/Procode: 90 KPR

Dear Mr. Desemberg:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

IX. Indications for Use: [Separate Page]

510(k) Number: ~~Not Applicable~~ K011111

Device Name: MXD 100 System, (Stationary X-ray)

Indications for Use:

The MXD 100 System is a stationary x-ray system intended for use in general Radiographic procedures by a licensed professional and designed to address a broad variety of radiographic procedures.

DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ___

(Optional Format 1-2-9

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011111